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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,108	12/20/2001	Timothy David Osslund	01017/38834F	7916

7590 01/24/2006

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EXAMINER

BASI, NIRMAL SINGH

ART UNIT PAPER NUMBER

1646

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

1. Amendment filed 11/7/05 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 62, 66, 75, 76, 79 and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Shaw (US Patent 4,904,584).

Applicant argues Shaw does not describe making lysine modifications in specific tertiary structure components of GCSF let alone an external loop. Applicant's arguments have been fully considered but are not found persuasive. Shaw teaches that all but 1 to approximately 6 of the original lysines can be deleted and/or replaced (see column 3, first paragraph and second paragraph, column 8 and column 14. Shaw (US Patent 4,904,584) discloses the "site-specific homogenous modifications of polypeptides" as well as substitutions of lysine residues 16, 23 and 34 with arginine (see, e.g., cols. 9-10, Table2, listing modification of lysine residues at positions 16, 23, 14 and 40). The lysine residues 16, 23, 34 and 40 disclosed by Shaw correspond to lysine residues 17, 24, 35 and 41 of instant application. SEQ ID NO:2 of instant application

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contains the optional N-terminal methionine residue at position 1, in contrast Shaw teaches the G-CSF molecule disclosed in Figure 4, which does not contain the optional N-terminal methionine. As such, the numbering used by Shaw is one amino acid lower than that used in instant specification. Shaw also teaches the modification of proteins by replacing naturally occurring lysine residues with non-lysines, preferably arginine, and substituting a lysine for a non-lysine residue. Abstract, col. 3, lines 36-43. The reference teaches that such modification is performed so as to control the attachment site of a molecule, such as PEG, to the protein, Col. 1. Shaw further teaches that in addition to modification of G-CSF by substituting the lysine residues with arginine, and other lysine residue can be used for PEG attachment. Therefore since Shaw teaches the same mutations disclosed in claims 62-65 it meets the limitations of said claims, absent evidence to the contrary.

Claim Rejection, 35 U.S.C. 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 62, 66, 75, 76, 79 and 81-83 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 62 and 66 are indefinite because "at least one amino acid residue is/are altered" to include "one or more lysines amino acid residues" and not "at

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least on amino acid sequence" altered" to include "one or more lysines amino acid residues". The amino acid sequence could be letters on a page identifying the amino acid residues of a polypeptide.

Further claims 62 and 75 are rejected for use of "at least one helix A amino acid sequence", "helix C amino acid sequence" and "helix D amino acid sequence". It is suggested "at least one helix A amino acid sequence" be changed to "at least one amino acid residue contained in helix A", to overcome the rejection. The other changes should be made accordingly to overcome the rejection.

Claim 76 is rejected for use of "at least two of helix A amino acid sequence", "helix C amino acid sequence" and "helix D amino acid sequence". It is suggested "at least two of helix A amino acid sequence" be changed to "at least two amino acid residue contained in helix A", to overcome the rejection. The other changes should be made accordingly to overcome the rejection.

Claim 79 is rejected for use of "at least three of helix A amino acid sequence", "helix C amino acid sequence" and "helix D amino acid sequence". It is suggested "at least three of helix A amino acid sequence" be changed to "at least three amino acid residue contained in helix A", to overcome the rejection. The other changes should be made accordingly to overcome the rejection.

Claims 80-83 are indefinite for depending on an indefinite base claim and fail to resolve the issues raised above.

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4. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nirmal S. Basi
Art Unit 1646
1/23/06


JANET L. ANDRES
SUPERVISORY PATENT EXAMINER